

PATENT

Docket No.: 20747/270 (ARDBW/P29257US)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Axel Thomson

Serial No. : 10/528,267

Cnfrm. No. : To Be Assigned

Filed : September 17, 2003

For : A METHOD OF PROTECTING A PATIENT
FROM POSSIBLE ADVERSE EFFECTS OF
INHIBITION OF THE SHH-SIGNALLING
PATHWAY BY SUPPRESSING
TESTOSTERONE OR ITS EFFECTS IN THE
PATIENT

Examiner:
To Be Assigned

Art Unit:
To Be Assigned

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §§ 1.97-1.98

Mail Stop: Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR §§ 1.97-1.98, applicant hereby brings to the attention of the United States Patent and Trademark Office, the enclosed references listed on the attached PTO/SB/08 form.

Pursuant to 37 C.F.R. § 1.98(a)(2)(ii), copies of the cited U.S. Patents (i.e., Reference Cite Nos. 1-2) are not enclosed. Copies of all other listed references (i.e., Reference Cite Nos. 3-67) are enclosed herewith.

Pursuant to 37 CFR § 1.97(b)(3), no fee is required. If additional fees are required, however, the Commissioner is hereby authorized to charge any fees to Deposit Account No. 14-1138.

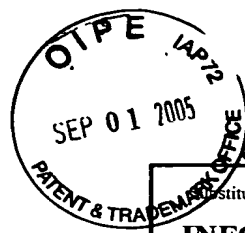
Respectfully submitted,

Date: August 29, 2005

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Date <u>8/30/05</u>	<u>Mary Burke</u> Mary Burke



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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
				Application Number	10/528,267
				Filing Date	September 17, 2003
				First Named Inventor	Axel Thomson
				Art Unit	To Be Assigned
Examiner Name	To Be Assigned				
Sheet	1	of	6	Attorney Docket Number	20747/270 (ARDBW/P29257US)

U.S. PATENT DOCUMENTS					
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		Number - Kind Code ² (if known)			
	1	US-4,946,779	08-07-1990	Kameda et al.	
	2	US-6,291,516 B1	09-18-2001	Dudek et al.	
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		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	3	WO 99/52534 A1	10-21-1999	Beachy et al.		
	4	WO 00/41545 A1	07-20-2000	Dudek		
	5	WO 01/27135 A2	04-19-2001	Beachy		
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	12	BITGOOD & McMAHON, " <i>Hedgehog</i> and <i>Bmp</i> Genes Are Coexpressed at Many Diverse Sites of Cell-Cell Interaction in the Mouse Embryo," <i>Dev. Biol.</i> 172:126-138 (1995)		
	13	BOSTWICK et al., "Prostatic Intra-Epithelial Neoplasia and Early Invasion in Prostate Cancer," <i>Cancer</i> 59:788-794 (1987)		
	14	CHEN et al., "Inhibition of Hedgehog Signaling by Direct Binding of Cyclopamine to Smoothed," <i>Genes Dev.</i> 16:2743-2748 (2002)		
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	16	CHIANG et al., "Cyclopia and Defective Axial Patterning in Mice Lacking <i>Sonic Hedgehog</i> Gene Function," <i>Nature</i> 383:407-413 (1996)		
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	18	CHOMCZYNSKI et al., "Single-Step Method of RNA Isolation by Acid Guanidinium Thiocyanate-Phenol-Chloroform Extraction," <i>Anal. Biochem.</i> 162:156-159 (1987)		
	19	COLE et al., "The EBV-Hybridoma Technique and Its Application to Human Lung Cancer," <i>Monoclonal Antibodies and Cancer Therapy</i> , Alan R. Liss, Inc., pp.77-96 (1985)		
	20	COTE et al., "Generation of Human Monoclonal Antibodies Reactive with Cellular Antigens," <i>Proc. Natl. Acad. Sci. USA</i> 80:2026-2030 (1983)		
	21	CUNHA & CHUNG, "Stromal-Epithelial Interactions-I. Induction of Prostatic Phenotype in Urothelium of Testicular Feminized (Tfm/y) Mice," <i>J. Steroid Biochem.</i> 14:1317-1321 (1981)		
	22	CUNHA et al., "Smooth Muscle-Epithelial Interactions in Normal and Neoplastic Prostatic Development," <i>Acta Anat.</i> 155:63-72 (1996)		

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	23	EPSTEIN, J.I., "Nonspecific Granulomatous Prostatitis vs. Infectious Granulomas," in <i>Differential Diagnosis in Pathology: Urologic Disorders</i> , Section 3: Prostate, New York, Igaku-Shoin Ltd., pp.74-136 (1992)	
	24	FREEMAN et al., "A Comparison of Basal Cell Markers Used in the Prostate," <i>Histopathology</i> 40:483-494 (2002)	
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	26	GAO et al., "Conversion from a Paracrine to an Autocrine Mechanism of Androgen-Stimulated Growth during Malignant Transformation of Prostatic Epithelial Cells," <i>Cancer Res.</i> 61:5038-5044 (2001)	
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	28	GENBANK ACCESSION NO. L38518 (1995)	
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	34	HAYWARD et al., "Epithelial Development in the Rat Ventral Prostate, Anterior Prostate and Seminal Vesicle," <i>Acta Anat.</i> 155:81-93 (1996)	

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	35	HAYWARD et al., "Interactions Between Adult Human Prostatic Epithelium and Rat Urogenital Sinus Mesenchyme in a Tissue Recombination Model," <i>Differentiation</i> 63:131-140 (1998)	
	36	INCARDONA et al., "The Teratogenic <i>Veratrum</i> Alkaloid Cyclopamine Inhibits Sonic Hedgehog Signal Transduction," <i>Development</i> 125:3553-3562 (1998)	
	37	KIM et al., " <i>Nkx3.1</i> Mutant Mice Recapitulate Early Stages of Prostate Carcinogenesis," <i>Cancer Res.</i> 62:2999-3004 (2002)	
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	39	KÖHLER & MILSTEIN, "Continuous Cultures of Fused Cells Secreting Antibody of Predefined Specificity," <i>Nature</i> 256:495-497 (1975)	
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	47	ORLANDI et al., "Cloning Immunoglobulin Variable Domains for Expression by the Polymerase Chain Reaction," <i>Proc. Natl. Acad. Sci. USA</i> 86:3833-3837 (1989)		
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	49	PATHI et al., "Comparative Biological Responses to Human Sonic, Indian, and Desert Hedgehog," <i>Mech. Dev.</i> 106:107-117 (2001)		
	50	PEPICELLI et al., "Sonic Hedgehog Regulates Branching Morphogenesis in the Mammalian Lung," <i>Curr. Biol.</i> 8:1083-1086 (1998)		
	51	PERRITON et al., "Sonic hedgehog Signaling from the Urethral Epithelium Controls External Genital Development," <i>Dev. Biol.</i> 247:26-46 (2002)		
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	53	ROELINK et al., "Floor Plate and Motor Neuron Induction by <i>vhh-1</i> , a Vertebrate Homolog of <i>hedgehog</i> Expressed by the Notochord," <i>Cell</i> 76:761-775 (1994)		
	54	RUIZ I ALTABA et al., "Gli and Hedgehog in Cancer: Tumours, Embryos and Stem Cells," <i>Nat. Rev. Cancer</i> 2:361-372 (2002)		
	55	SCHNEIDER et al., "Targeted Disruption of the Nkx3.1 Gene in Mice Results in Morphogenetic Defects of Minor Salivary Glands: Parallels to Glandular Duct Morphogenesis in Prostate," <i>Mech. Dev.</i> 95:163-174 (2000)		
	56	STONE et al., "The Tumour-Suppressor Gene <i>Patched</i> Encodes a Candidate Receptor for Sonic Hedgehog," <i>Nature</i> 384:129-134 (1996)		
	57	SUGIMURA et al., "Keratinocyte Growth Factor (KGF) Can Replace Testosterone in the Ductal Branching Morphogenesis of the Rat Ventral Prostate," <i>Int. J. Dev. Biol.</i> 40:941-951 (1996)		
	58	SUGIMURA et al., "Morphogenesis of Ductal Networks in the Mouse Prostate," <i>Biol. Reprod.</i> 34:961-971 (1986)		

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	59	SUKEGAWA et al., "The Concentric Structure of the Developing Gut is Regulated by Sonic Hedgehog Derived from Endodermal Epithelium," <i>Development</i> 127:1971-1980 (2000)	
	60	TAKEDA et al., "Construction of Chimaeric Processed Immunoglobulin Genes Containing Mouse Variable and Human Constant Region Sequences," <i>Nature</i> 314:452-454 (1985)	
	61	THOMSON & CUNHA, "Prostatic Growth and Development are Regulated by FGF10," <i>Development</i> 126:3693-3701 (1999)	
	62	THOMSON et al., "Analysis of Growth Factor and Receptor mRNA Levels During Development of the Rat Seminal Vesicle and Prostate," <i>Development</i> 124:2431-2439 (1997)	
	63	THOMSON et al., "The Role of Smooth Muscle in Regulating Prostatic Induction," <i>Development</i> 129:1905-1912 (2002)	
	64	TOTTEN et al., "Microscopic Differential Diagnosis of Latent Carcinoma of Prostate," <i>Arch. Pathol.</i> 55:131-141 (1953)	
	65	WANG et al., "Cell Differentiation Lineage in the Prostate," <i>Differentiation</i> 68:270-279 (2001)	
	66	WINTER & MILSTEIN, "Man-made Antibodies," <i>Nature</i> 349:293-299 (1991)	
	67	WOJNO et al., "The Utility of Basal Cell-Specific Anti-Cytokeratin Antibody (34 β E12) in the Diagnosis of Prostate Cancer," <i>Am. J. Surg. Pathol.</i> 19(3):251-260 (1995)	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	10/528,267
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				First Named Inventor	Axel Thomson
				Group Art Unit	To Be Assigned
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Sheet	3	of	6	Attorney Docket Number	20747/270 (ARDBW/P29257US)

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	23	EPSTEIN, J.I., "Nonspecific Granulomatous Prostatitis vs. Infectious Granulomas," in <i>Differential Diagnosis in Pathology: Urologic Disorders</i> , Section 3: Prostate, New York, Igaku-Shoin Ltd., pp.74-136 (1992)	
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